Autoverification Approved in California

Assembly Bill 2156 was signed into law on September 18, 2006 and implemented on January 1, 2007. This new law is codified under Business and Professions Code (BPC) 1209.5 and it authorizes laboratories to use autoverification to report test results. This law will supersede Department of Health Services regulations enacted over 30 years ago (17CCR 1050 (h)) which requires all clinical laboratory test results to be critically reviewed by a licensed person prior to release.

Certain requirements must be met, however, before autoverification can be adopted by a laboratory.

- First, the laboratory director or authorized designee is responsible for establishing explicit reporting criteria for autoverification. These reporting criteria use a computer algorithm to make decisions on whether a test result is accurate and can be reported, or whether it should be held up and re-evaluated.
- Second, autoverification must be validated to make sure the computer algorithm gives the same outcome as manually released results. This means samples must be run to test each decision point in autoverification. A laboratory cannot simply buy some middleware and drop it into their laboratory IT system and use it.
- Third, re-validation of autoverification must be done at least annually, or any time there is a change of the system.
- Fourth, a licensed person must be physically present wherever autoverification is being performed. This person must be competent in the autoverified tests, and shall be responsible for accuracy and reliability of results reported.

Some FAQs about autoverification.

- Can a competent unlicensed lab assistant run an autoanalyzer using autoverification? Yes, if a licensed person is onsite while testing is done.

- What kind of supervision does the lab assistant need? Direct and constant, onsite, while testing is done.

- Who makes the decisions on results held up in autoverification, that is, not reported? Can the lab assistant do this? No, the licensed person must evaluate those results not autoverified, that is, those results held up as outside the algorithm. The licensed person must decide how to handle these.

- In autoverification, does a lab need to repeat all results outside normal range? No, if they otherwise meet the reporting algorithm.

- Can we say "result verified" if it is abnormal and reported by autoverification? Can we say "result autoverified"? This is up to the laboratory director. It is the laboratory director who sets reporting criterion.

To view the statute, [click here.](#)